

## Appendix

Table A. Description of the Take Charge session

Aims	Encourage a sense of purpose for life after stroke Emphasise autonomy Encourage a sense of mastery in the management of their life after stroke Identify their key support people
Components	Re-establishing identity – Who I Really Am My Hopes and Fears My Best Day Goal setting and risk management
Content of Research Clinician training	Make a connection with the person Ensure that all ideas came from the person with stroke Say little themselves unless reflecting back what the person with stroke had said Not to ask any direct questions or make 'helpful suggestions' Having nothing written down at the end of the session was acceptable

For a full description and materials, visit [www.mrinz.ac.nz/programmes/stroke](http://www.mrinz.ac.nz/programmes/stroke) where the booklet and training manual are available for free download. Here is the introduction from the training manual:

### Introduction to the Take Charge process

The Take Charge session facilitates the process where the Person (and their support people) 'Take Charge' of their life after stroke. The aim is for the Person to take on the responsibility for their own rehabilitation (i.e. self-rehabilitation) and the process of re-establishing themselves as a person independent of the effects of the stroke. Previous research by our group has shown that 'Taking Charge' is something that people want, yet they feel stuck because either they haven't worked out how to do so or feel they have to do what other people tell them.

We know that many people in the first few months after stroke are overwhelmed by the stroke itself, even if the problems caused by the stroke aren't severe. There is a combination of physical things ('I have trouble doing...'), psychological things ('Does this mean my life is changed forever?...') and life things ('What about my family? My job?...'). Traditional rehabilitation tends to focus on the physical things with the (unsaid) message that once the physical things are better everything else

will fall in to place. Unfortunately, most of the physical improvement has finished by 12 weeks after the stroke, often sooner, and although people improve after this time, much of the improvement is by adaptation and compensation. The emphasis on physical things may prevent the person grappling with the more important psychological and life questions. The 'Take Charge session' starts from the big life questions and assists the person to identify and explore the main issues for that person.

People who successfully 'Take Charge' have some of the following in common:

- i. They can see the big picture
- ii. They can express who they are as a person
- iii. They have the attitude that anything is possible
- iv. They have support from someone (usually a family member)

The Take Charge intervention motivates people to tap into these resources if already present, or to try and develop them if they don't.

Table B: Schedule of assessments

	<b>Time point</b>	Acute stroke	Randomisation (baseline 2-16 weeks after stroke)	6 months after acute stroke	12 months after acute stroke
	<b>Method</b>	Retrospective casenote review	Face-to-face	Postal or electronic questionnaire	Face-to-face
<b>Assessment name</b>					
Barthel Index <sup>a</sup>		X	X	X	X
Demographic information			X		
Medications <sup>b</sup>			X		
Frenchay Activities Index <sup>c</sup>			X	X	X
Modified Rankin Scale <sup>d</sup>			X	X	X
Short Form12 Physical Component Summary (PCS)score <sup>e</sup>			X	X	
Short Form36-PCS <sup>f</sup>					X
Risk factor assessment <sup>g</sup>			X		
Carer Strain Index <sup>h</sup>				X	X
Euroqol 5D <sup>i</sup>				X	X
Admission to hospital				X	X <sup>j</sup>
Recurrent stroke				X	X <sup>j</sup>

<sup>a</sup> Standardised measure of activities of daily living (ADL) on a scale 0-20 with lower scores reflecting fewer activities, <sup>b</sup> including fluoxetine because of ongoing randomise controlled trials of fluoxetine vs placebo in stroke rehabilitation, <sup>c</sup> standardised measure of advanced ADL/participation on a scale 0-45 with lower scores reflecting fewer activities, <sup>d</sup> standardised measure of health status/independence on a scale 0-5 with lower scores reflecting greater independence, <sup>e</sup> standardised measure of health related quality of life on a scale 0-100 with higher scores reflecting better quality of life, <sup>f</sup> standardised measure of health related quality of life on a scale 0-100 with higher scores reflecting better quality of life, <sup>g</sup> comprising direct measurement of heart rate, rhythm,

blood pressure, height and weight and smoking history, <sup>h</sup> standardised measure of carer strain on a scale 0-13 with higher scores reflecting increased strain, <sup>i</sup> standardised measure of quality of life with five dimensions scored at five levels and a visual analogue scale (VAS) of health status on a scale 0-100 with higher scores reflecting better health, <sup>j</sup> checked by casenote review.

## The Short Form 36 (SF-36) and Short Form 12 (SF-12)

The SF-36 is a measure of self-rated health-related quality of life. It comprises 36 questions grouped into eight fields: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health. The Physical Component Summary score (PCS) is calculated by an algorithm that weights the scores for five fields with a 'physical' flavour while the Mental Component Summary score (MCS) is derived from fields with a 'mental/emotional' flavour (see table below). The weightings have been applied so that the mean PCS and MCS is 50 with standard deviation of 10 for scores from population surveys. Higher scores are better. For unselected people with stroke 12 months after the index event, mean PCS in various studies is 35-40, depending on initial severity. The PCS can also be derived from the Short Form 12 (12 questions only drawn from the original 36).

Subscales measured	Contribution to	Range of scores
Physical Functioning	Physical Component Summary (PCS) score	0 – 100*
Role Physical		
Bodily Pain		
General Health	Both PCS and MCS scores	0 – 100*
Vitality		
Social Functioning	Mental Component Summary (MCS) score	
Role Emotional		
Mental Health		

\*Population-derived mean score = 50, standard deviation = 10.

Ware J., Snow K., Kosinski M., Gandek B., SF-36 Health Survey Manual and Interpretation Guide, The Health Institute, New England Medical Centre, 1993

Bohannon RW, Maljanian R, Lee N, Ahlquist M. Measurement properties of the short form (SF)-12 applied to patients with stroke. Int J Rehabil Res 2004;27:151-4.

Table C: Reasons for exclusion

Reason for exclusion	Totals
<b>Did not meet inclusion criteria</b>	<b>2255</b>
Ethnicity	598
Fully recovered	366
Not stroke diagnosis	357
Institutional care	318
Unable to consent	141
Required interpreter	139
Life expectancy < 12m	131
Pre-stroke modified Rankin Score > 2	40
Outside 16 week window	31
Lives in different health district not in study	70
Non-New Zealand resident	64
<b>Declined to participate</b>	<b>373</b>
Declined	336
Lives too far away	37
<b>Other</b>	<b>58</b>
Discharged prior to verbal consent for contact	6
Unable to contact	26
Involved in another study	26
<b>Total excluded</b>	<b>2686</b>

Table D. Differences in SF36 PCS by sub-group: any Take Charge intervention vs control

Sub-group		
Age <75	Age 75+	P Interaction
1.71 (-0.90 to 4.33)	3.99 (1.13 to 6.85)	0.40
<b>Baseline fluoxetine use</b>	<b>No baseline fluoxetine use</b>	
7.19 (1.36 to 13.0)	2.35 (0.26 to 4.45)	0.28
<b>Significant communication disorder</b>	<b>No significant communication disorder</b>	
3.42 (-9.97 to 16.8)	2.79 (0.77 to 4.81)	0.81
<b>Significant cognitive disorder</b>	<b>No significant cognitive disorder</b>	
3.83 (-7.81 to 15.5)	2.93 (0.90 to 4.95)	0.65
<b>Male</b>	<b>Female</b>	
0.36 (-2.19 to 2.92)	6.39 (3.38 to 9.39)	0.01
<b>Living alone</b>	<b>Not living alone</b>	
3.66 (0.40 to 6.92)	2.39 (-0.08 to 4.85)	0.04
<b>Support person</b>	<b>No Support person</b>	
4.50 (2.20 to 6.80)	-1.44 (-5.31 to 2.43)	0.02
<b>Ischaemic stroke</b>	<b>Haemorrhagic stroke</b>	
2.81 (0.74 to 4.88)	3.77 (-2.51 to 10.1)	0.89
<b>Received thrombolysis</b>	<b>Didn't receive thrombolysis</b>	
1.57 (-3.86 to 6.99)	3.15 (0.87 to 5.43)	0.78
<b>Received thrombectomy</b>	<b>Didn't receive thrombectomy</b>	
NA	NA	0.30
<b>Tertiary centre</b>	<b>Not a tertiary centre</b>	
2.71 (0.41 to 5.01)	3.39 (-0.45 to 7.24)	0.67
<b>Barthel Index category</b>		
<b>Mild (15-20)</b>	<b>Moderate (10-14)</b>	<b>Severe (0-9)</b>

3.15

2.39

2.13

0.89

(0.67 to 5.62)

(-2.10 to 6.88)

(-2.65 to 6.91)

SF-36 PCS = Physical Component Summary of the Short Form 36

Table E: Ordinal regression of the Modified Rankin Scale (mRS)

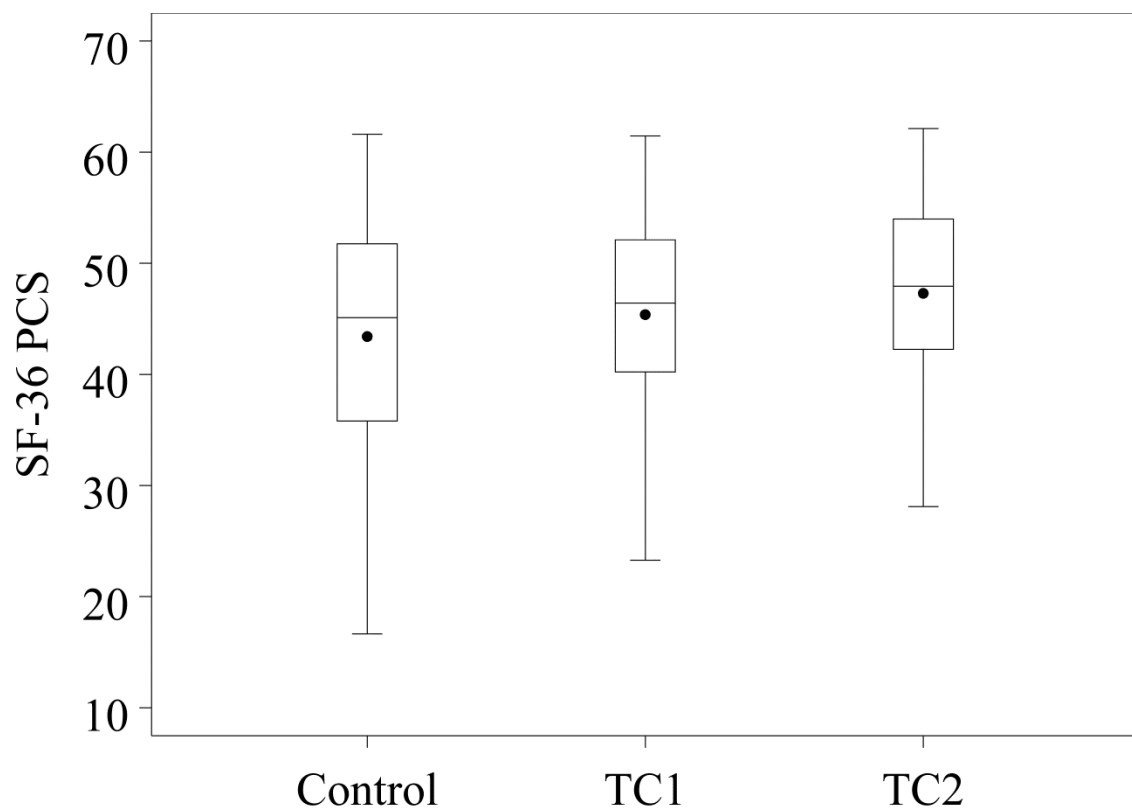
Variable	N/N (%)			Odds Ratio (95% CI) <sup>1</sup>	P <sup>2</sup>
	Control	TC1	TC2	TC2+TC1 versus control	
mRS at 12 months	N=128	N=126	N=133	0.84 (0.57 to 1.24) P=0.37	0.48
0	18 (14.1)	20 (15.9)	22 (16.5)		
1	60 (46.9)	55 (43.7)	64 (48.1)		
2	25 (19.5)	33 (26.2)	34 (25.6)		
3	20 (15.6)	16 (12.7)	11 (8.3)		
4	5 (3.9)	2 (1.6)	2 (1.5)		

TC1 = participants randomised to receive one Take Charge session. TC2 = participants randomised to receive two Take Charge interventions 6 weeks apart. mRS = modified Rankin Scale.

1. An OR of <1 implies a better outcome (lower scores better)

2. P-value for main effect of randomisation

Figure A: Primary outcome by allocation



SF-36 PCS = Physical Component Summary of the Short Form 36. TC1 = participants randomised to receive one Take Charge session. TC2 = participants randomised to receive two Take Charge interventions 6 weeks apart. The filled circle is the mean, the horizontal lines are the 25<sup>th</sup>, 50<sup>th</sup> (median), and 75<sup>th</sup> percentiles, and the whiskers extend from the minimum to maximum values.

## Description of the Take Charge Intervention using the TiDIER framework

### 1. Brief name:

Take Charge session

### 2. Why

Our qualitative research identified Taking Charge as a central theme to recovery and life for people with stroke. We incorporated components of Self Determination Theory (purpose, autonomy, and connectedness) with Maori principles of *tinorangatanga* (self-determination) and *hauora* (health – a holistic approach involving physical, mental, spiritual, and family).

The Maori and Pacific Stroke Study (MaPSS) showed that the first iteration of the Take Charge session improved quality of life, dependency, and caregiver strain at 12 months following stroke. We built upon this result by refining the intervention with a booklet to guide the session.

### 3. What materials

Take Charge booklet available online at [www.mrinz.ac.nz/programmes/stroke](http://www.mrinz.ac.nz/programmes/stroke)  
First three pages invite the person with stroke to think about themselves, the things in life which are important and meaningful to them, their hopes and their fears  
The final pages are spaces to set goals under headings e.g. physical, secondary prevention

Training manual used to train Take Charge session facilitators available online at [www.mrinz.ac.nz/programmes/stroke](http://www.mrinz.ac.nz/programmes/stroke).

### 4. What procedures

Baseline assessments including: modified Rankin scale, Barthel Index, Frenchay Activities Index, AMP-C score, PHQ-2, Euroqol EQ-5D-5L, SF-12, PAM

Take Charge session guided by booklet. Facilitator trained to ask questions, allow silences, and reflect ideas. Specifically trained to not deliver advice, suggestions, opinions, or medical expertise.

### 5. Who provided

Research clinicians trained in delivering Take Charge. In the trial, these were mostly research nurses, but also included stroke nurses, physiotherapists, and an occupational therapist.

All research clinicians received training in using the assessment measures and how to deliver the Take Charge session. They were further supported by regular e-mail, telephone, and teleconference contact to address any issues that arose.

### 6. Mode

Take Charge was delivered face-to-face individually to the participant. Family members could be present at the participant's discretion but were not directly involved in the session.

## **7. Where**

The Take Charge session was delivered at the participant's home.

## **8. When and How Much**

Any time from 2 to 16 weeks after stroke, dependent upon participant choice, availability, and ability to engage (e.g. postponed if too fatigued). Each session took between 30 to 60 minutes to complete.

Participants allocated to two Take Charge sessions received a second Take Charge session approximately six weeks after the first. The second session also repeated the baseline assessments.

## **9. Tailoring**

The session was designed to be led by the person with stroke. The booklet was a guide that could be adhered to as loosely or as strongly as the person chooses. The facilitator's role was to build a connection with the person with stroke, to be inquiring but non-directional, and to listen. Page 4 of the booklet (Draw your best day) could be modified to be done as a visualisation exercise. The booklet could be left blank at the end of a session, and it was left with the person and family to do with as they liked.

## **10. Modifications**

### *Timing of the intervention*

We estimated that the majority of our intervention visits would occur within 6-16 weeks after stroke, however, we increased this window to 2-16 weeks after stroke to allow for greater inclusion of people with mild stroke who were discharged within a few days of admission of hospital. As long as they reported ongoing symptoms (not completely recovered from stroke) and were prepared to participate and have a home visit, this visit went ahead.

### *Length of the intervention*

No specific modifications were made for people with mild cognitive or communication difficulties apart from allowing unlimited time for the session(s).

## **11. How well (planned)**

Intervention adherence or fidelity was not formally assessed by an external observer for two main reasons. First, we felt that this would risk compromising the therapeutic relationship between the facilitator and participant, and second, external observation or video-taping of the intervention in the participant's home had not been approved by the ethics committee. Instead, research clinicians wrote

notes at the end of each session describing 'what went well' and 'what did not go well', which were part of the source data forms that were sent back to the research institute and reviewed by the investigators. These were followed-up by the investigators who supported the research clinicians in person or by telephone.

Other strategies used to maintain and improve fidelity were the use of monthly teleconferences between all the research clinicians and the investigators, during which the important components of the Take Charge intervention were reiterated, and research clinicians were able to share with each other techniques/phrases they had developed to improve their adherence to the intervention. We also sent monthly newsletters with links to recommended reading.

## Taking Charge after Stroke study Statistical analysis plan

From ANZCTR website

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=369519&isReview=true>

SAP described at initial registration 2/11/2015 prior to first participant enrolment.

### Taking Charge after Stroke: statistical plan

Sample size calculation: In the Maori and Pacific Stroke Study (MaPSS) the root mean square error for PCS (the primary endpoint) was 10.8. The clinically significant difference for PCS has been estimated in non-stroke populations to be 5. Our analysis of PCS scores from the MaPSS study suggests a clinically significant difference is approximately 2.5. Thus a shift from 40 to 42.5, or 42.5 to 45 is a very meaningful clinical improvement for a person with stroke.

However, for the purposes of a study size calculation we have used a change of 5 in the PCS. This requires a total sample size of 360, 120 in each of three arms, and has 90% power to detect this difference. With provision for 10% drop out we plan to recruit 400 participants.

Each analysis is organised as: Comparison; Outcome variable; Time point after stroke; Analysis tool

#### Primary analysis

1.1 Take Charge vs control (2:1 participants); PCS of SF36 with the two pre-specified comparisons, if there is overall evidence of a difference in mean values: All TCS compared to control and secondly TCS high dose compared to TCS low dose; 12 months; ANOVA

#### Secondary analyses

2.1 Take Charge vs control (2:1 participants); PCS of the SF36, adjusted for the following baseline variable/s: Barthel Index Score three days after stroke, baseline PCS (using SF12), age, gender, living alone with the two pre-specified comparisons, if there is overall evidence of a difference in mean values: All TCS compared to control and secondly TCS high dose compared to TCS low dose; 12 months; ANCOVA

2.10 Pre-specified subgroup analyses using an interaction term between randomised treatment and each of: Barthel Index at 3-5 days after stroke grouped severe (0-9), moderate (10-14) and mild (15-20), site ((a) all centres, (b) tertiary centres vs not), age (<75 years, 75+ years), gender, living alone, main support person (yes/no), type of stroke (ischaemic vs haemorrhage), received thrombolysis or thrombectomy (yes/no), taking fluoxetine at baseline (yes/no), significant communication disorder (vs none/mild), significant cognitive disorder (vs none/mild), Autonomy/Mastery/Purpose/Connectedness (AMP-C sum) questions, Patient Activation Measure;

12 months; ANCOVA

2.11 Take Charge vs control, treating PCS of the SF36 as an ordinal scale variable with up to 5 'bands' of scores, 12 months, ordinal logistic regression.

2.12 Take Charge vs control, treating PCS of the SF36 as a dichotomous variable, 12 months, logistic regression

2.2 Take Charge vs control Dependency mRS (0-5) treated as an ordinal scale variable; 12 months; Ordinal logistic regression

2.3 Take Charge vs control Dependency dichotomised as (mRS 0 to 2 compared to 3 to 5, for consistency with past literature. Note that if the proportional odds assumption is correct for 2.2 that this estimate will be the same; 12 months; Estimation of Relative Risk

2.4 Take Charge vs control; Death; 12 months; Estimation of Relative Risk

2.5 Take Charge vs control; Death or dependency based on mRS 0 to 2 compared to 3 to 5; 12 months;

Estimation of Relative Risk
2.6 Take Charge vs control; Carer Strain Index treated as a continuous variable; 12 months; ANOVA
2.7 Take Charge vs control; EuroQol (Visual Analogue Scale) treated as a continuous variable; 12 months; ANOVA
2.8 Take Charge dose response; PCS of the SF36 treating the TCS dose (none, low dose, and high) as a continuous predictor; 12 months; ANCOVA
2.9 Take Charge vs control; Barthel Index as continuous variable; 12 months; ANOVA
2.10 Take Charge vs control; Frenchay Activities Index as continuous variable; 12 months; ANOVA
2.11 Take Charge vs control; Patient Health Questionnaire-2 as continuous variable; 12 months; ANOVA
2.12 Autonomy/Mastery/Purpose/Connectedness (AMP-C) score as continuous variable; 12 months; ANOVA
2.13 Take Charge vs control; contact with rehabilitation service (yes/no); 12 months; estimation of relative risk
2.14 Take Charge vs control; Each of the analyses described above; 6 months; As per 12month analysis
2.15 Take Charge vs control; Hospitalisations; 12 months; estimation of relative risk
2.16 Take Charge vs control; recurrent stroke; 12 months; estimation of relative risk
2.17 Take Charge vs control; Medication Adherence Questionnaire (MAQ) score as a dichotomised variable (0 vs 1-4); 12 months; estimation of relative risk
Meta-analysis 3.1
Take Charge vs control, combining individual patient data from Taking Charge after Stroke Study and Maori and Pacific Stroke Study; PCS; 12 months Linear Mixed Model
Meta-analysis 3.2 Take Charge vs control, combining individual patient data from Taking Charge after Stroke Study and Maori and Pacific Stroke Study; dependency (mRS 0-5) ordinal shift; 12 months; Generalised Linear Mixed Model
Economic analysis
4.1 Take Charge vs control; EuroQol health utility; 12 months; ANOVA
4.2 Take Charge vs control; Short Form 6D health utility; 12 months; ANOVA
4.3 Take Charge vs control; Dollars per QALY lost/saved; 12 months; Cost effectiveness analysis
4.4 Take Charge vs control; Multivariable; 12 months; Comprehensive cost consequence analysis (multiple costs, multiple outcome endpoints)
5.0 Take Charge vs control; Multivariable; 12 months; Serious adverse events